June 21, 2002

Ms. Evangeline Tsibris Cummings
Environmental Protection Agency
Office of Environmental Information
Mail Code 2842T
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Attn: Docket ID No. OEI-10014

Re: CPDA Comments on EPA Data Quality Guidelines
Pursuant to EPA's April 30, 2002 Federal Register Notice (67 Fed. Reg. 21234)

Dear Ms. Cummings:

We at the Chemical Producers and Distributors Association (CPDA) appreciate the opportunity to comment on EPA's (the Agency) Draft Data Quality Guidelines.

By way of background, CPDA is a voluntary, non-profit organization of about 90 companies engaged in the formulation, manufacturer, distribution, and sale of some $6 billion worth of generic products used on food, feed, and fiber crops and in the care of lawns, gardens and turf. Many of our members are involved in the development and sale of adjuvants and inerts used to increase the efficacy of crop protection formulations as well as a variety of copper-based pesticide products. As such, EPA rules, regulations, and guidelines affect our member companies significantly.

In our initial comments filed in mid-March, CPDA identified EPA's responsibility to the public to protect and promote human and environmental health as imparting on the Agency a tremendous responsibility to ensure the quality of the data upon which the Agency relies. As an extension of the Agency's significant purpose, CPDA urged the Agency to maximize the quality of information *before* distribution, in order to minimize the occurrence of complaints and corrections and maintain the public trust.

We commend the Agency on recognizing the importance of quality information, and for the Agency's demonstration of this commitment through its increasing transparency. However, we feel that the Agency's Draft Data Quality Guidelines fall short of OMB's mandates in several areas. Below, we point out several instances where the Agency's Guidelines do not fully address the requirements of the Data Quality Act, and we respectfully recommend ways in which the Agency can build on principles and procedures already in place.

As an overview, CPDA recommends EPA develop the Draft Guidelines in the following ways:

- By expanding and refining its existing procedures, EPA can maximize quality efficiently and effectively;
- By providing the analytical factors the Agency uses to determine whether information is "influential," the EPA will create living Guidelines that can address developing areas of information;
- By focusing on pre-dissemination review, the Agency can conserve resources while reducing reliance on complaint and correction mechanisms; and
- By implementing a "triage" system, the Agency can ensure that data causing the most harm can be addressed most expeditiously.

Overview, Scope, and Applicability (Section 1)

1.1 What is the purpose of these guidelines?

EPA's strong introduction, i.e., "[t]hese guidelines describe EPA's policy and procedures for *reviewing* and *substantiating* the quality of information *before* EPA disseminates it (lines 397-98, emphasis added) over-states the information contained in the Agency's guidelines. Instead of demonstrating how the Agency will improve its existing procedures to ensure high-quality information, the Guidelines maintain that the Agency's existing procedures satisfy quality requirements and focus on the numerous instances where the Agency feels the policies should not apply. The Agency's focus on exemptions is inconsistent with the goal of ensuring quality.

The Agency statement that the guidelines "are not legally enforceable and do not create any legal rights or impose any legally binding requirements or obligations on EPA" is an attempt to disclaim the Agency's duty to maximize information quality. (lines 402-3) In a June 10, 2002 memorandum to the President's Management Council (OMB Memorandum), OMB cautions that "statements regarding judicial enforceability might not be controlling in the event of litigation." Regardless of "litigation-oriented disclaimers. . . agency guidelines should not suggest that agencies are free to disregard their own guidelines." CPDA agrees with OMB that the attempt to disclaim data quality duties is not only ineffective, but also weakens the guidelines by focusing on possible exemptions.

1.2 When do these guidelines apply?

Under the Data Quality Act, "information" and "dissemination," trigger data quality scrutiny. CPDA commends the Agency for pointing out that (1) preliminary information, if relied upon or disseminated, is subject to data quality scrutiny (lines 423-24) and (2) information is disseminated when the Agency relies upon the information to make "support or represent EPA's viewpoint, to formulate or support a regulation, guidance, or other Agency decision or position" (lines 429-31).

While EPA suggests "[f]actors such as imminent threats . . . may limit or preclude applicability" (lines 418-20) of data quality scrutiny, CPDA points out that security threats may actually impose increased duties to protect information. In this time of increased security awareness, the Agency should consider the impact of releasing information that has been compromised through cyber terror. The Agency should implement safeguards for protecting information integrity, considering factors such as what technology is available, the Agency's available resources, and the potential influence of compromised information.

1.3 What is not covered by these guidelines?

While there will be instances when data quality procedures will not be triggered (i.e., where there is no "dissemination"), CPDA believes the Agency makes several over-broad assertions as to when the data quality procedures would not apply.

First, CPDA disagrees that EPA may broadly exempt all correspondence, with individuals or persons (line 474), from data quality review. (lines 474-81) The triggers for data quality protection are "information" and "dissemination" and should not be circumvented via correspondence. If the correspondence relies on or describes Agency policy, not only must the information on which the policy is based be subject to data quality scrutiny, but the correspondence, too, must comply with data quality procedures. By the same reasoning, CPDA believes the exemption for press releases is also over-broad. (lines 482-485) That is, letters and press releases describing Agency policy or decisions must be accurate and not misleading.

1.4 What happens if information is initially not covered by these guidelines, but EPA subsequently disseminates it to the public?

CPDA commends the Agency for recognizing the broad implications of "dissemination." The Agency demonstrates a commitment to reliance on high-quality data when it acknowledges that the information underlying all Agency decisions disseminated on or after October 1, 2002 must undergo data quality scrutiny.

1.5 How does EPA ensure the objectivity, utility, and integrity of information that is not covered by these guidelines?

EPA's Draft Data Quality Guidelines include a discussion of the Agency's general policy regarding information quality. The Agency states that information quality standards are linked to "the nature and timeliness of the planned and anticipated uses" and that "the need to ensure the quality of EPA information is not necessarily dependent upon any plans to disseminate the information." (lines 562-66) CPDA commends the Agency for its stated commitment to data quality; we further hope that the Agency's upcoming Data Quality Guidelines provide detailed information on the Agency's data quality procedures.

Defining Information Quality (Section 2)

2.1 What is "quality" according to the guidelines?

The Agency should not rely solely on the OMB Guidelines for a definition of quality. (lines 569-78) Quality under the Data Quality Act is not merely the sum of its three components (objectivity, integrity, utility), but should have specific meaning and applications pertinent to EPA's regulatory responsibilities.

The Agency must define the elements of quality in order for it guidelines to mean anything at all. Without standards, all information could be "quality" information, thus circumventing the purpose of the Data Quality Act. OMB's Memorandum expresses the concern that agencies might avoid defining quality in order to avoid responsibility: "Each agency needs to adopt explicitly each aspect of each definition of quality, utility, objectivity, and integrity as an agency information quality standard. Otherwise, there will be no benchmark against which a public complainant will be able to suggest non-attainment." We at CPDA do not believe that the Agency has accomplished what OMB has asked the Agency to do.

Ensuring and Maximizing Information Quality (Section 3)

3.1 How does EPA ensure and maximize the quality of disseminated information?

OMB's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (OMB Guidelines) encourage agencies to *develop* existing practices to meet the higher threshold of examination required by the Data Quality Act. Presumably, the OMB Guidelines advocate for the development of existing procedures for two reasons: (1) so as not to burden the agency with inefficient, redundant procedures, and (2) in an effort to ensure quality, to improve upon the mechanisms which the agency already has in place, rather than developing separate procedures which may lead to loopholes and "cracks" through which sub-standard data can slip.

In its Memorandum, OMB "stress[es] that a mere description of current practices – however good – is not a substitute for explicit performance goals." The Agency's Draft Guidelines identify existing procedures and imply that the existing procedures, which are not fully described, are sufficient to meet the requirements of the Data Quality Act. CPDA encourages EPA to identify the particular procedures the Agency will utilize and detail the specific ways in which the procedures will be developed to meet the requirements of the Data Quality Act. We would like to emphasize that OMB's Memorandum specifies that agency guidelines should state quality as a "performance goal" and take "steps" to incorporate data quality criteria.

3.2 How does EPA define influential information for these guidelines?

The Agency's Draft Guidelines provide useful guidance for identifying "influential" information. The Guidelines provide examples of influential information, and CPDA commends the Agency on developing these categories. We are pleased to see that, for example, "highly controversial" (lines 599-600) issues will trigger closer inspection of information before release or reliance by the Agency. Both the Agency and the public will benefit from this increased scrutiny as the Agency demonstrates its commitment to quality data.

While the categories of influential information provide a useful starting point, CPDA urges the Agency to further develop the "case-by-case" example. (lines 624-28) In particular, the Guidelines should identify the factors the Agency will consider in assessing whether information is "influential." Listing factors will create a "living document," that will be relevant to emerging issues and classes of information. Such a list of factors will allow stakeholders to consider for themselves the likely standard to which their submissions will be held, and will reduce the Agency's burden for Guideline updates.

Systematic evaluation of the "influence" the publication of information will incur should be an essential element of pre-dissemination screening. The OMB Guidelines require the Agency to consider the impact disseminating information will have on public policies and private sector decisions. The broad scope of EPA's charge to protect human health and the environment points to the influence the Agency's publications have on both public policy and private decisions. The gravity of EPA's influence in setting environmental policy underscores the need for EPA publications to be science-based.

EPA should pay special care to ground-breaking information, that is, information which is controversial, unproven, or widely disputed by scientists. EPA should reasonably expect the public to rely on the Agency's judgment of developing issues, and thus, the Agency should take special care in ensuring that only data of the highest quality is issued. The lack of public knowledge about an issue makes the quality of EPA's published position even more important.

For example, EPA's Office of Science Coordination and Policy (OSCP) is scheduled to publish by December 31, 2002, a preliminary list of chemicals that may undergo endocrine disruption screening. Obviously, the list will contain only very preliminary information, since the chemicals appearing on the list will not have been screened; in fact, the screens themselves are not due to be developed until *after* the publication of this preliminary list. EPA's Data Quality Guidelines should anticipate the potential influence of preliminary information. While the potential impacts on private behavior are immense, the integrity of information not yet scientifically-proven is suspect. EPA should always weigh these factors when evaluating the "influence" published information may have.

3.3 How does EPA ensure and maximize the quality of "influential" information?

Both the OMB Guidelines as well as the Agency's Draft Guidelines recognize the need for increased transparency when dealing with "influential" information. As above, CPDA is concerned that the Agency's Draft Guidelines do not define the increased transparency in an agency-specific way; rather, the Agency's Guidelines simply re-state the parameters the OMB Guidelines set forth. We do not believe this approach satisfies OMB's prescription and respectfully urge the Agency to demonstrate how the Agency intends to increase transparency with respect to influential information. We recognize the Agency's need to be flexible in developing criteria for a spectrum of initiatives; however, consistent with increased transparency, stakeholders should know how the Agency will treat influential information.

According to OMB's Guidelines, influential information triggers "reproducibility" as evidence of an agency's transparency, or, if reproducibility is not possible for compelling

reasons, the agency must perform "especially vigorous robustness checks." CPDA believes that this stringent standard creates a presumption of non-transparency when the Agency does not achieve reproducibility. In other words, when the Agency relies on influential information that is not reproducible, the Agency should bear the burden of proving its robustness checks are in fact "especially rigorous."

3.4 How does EPA ensure and maximize the quality of "influential" scientific risk assessment information?

EPA performs influential risk assessments pursuant to the laws the Agency administers. CPDA would like to specifically commend one Agency department for its commitment to quality and transparency: EPA's Office of Pesticide Programs (OPP) has demonstrated excellence in transparency through its extensive, open dialogue with stakeholders in the Committee to Advise on Reassessment and Transition (CARAT) work group. We recommend the Agency generally adopt the principals of transparency and reproducibility utilized by OPP in its Cumulative Risk Assessment process.

OMB's Guidelines require that influential information be reproducible in order "[t]o cultivate a consistent agency commitment to transparency about how analytic results are generated. . . " (67 Fed. Reg. 8451, 56) Stakeholders should have access to the underlying methods, assumptions, and equations used in performing risk assessments. The OMB Memorandum "recommend[s] that agencies, in generating (or contracting to generate) influential information for dissemination, encourage arrangements that will permit appropriate public access to the related original and supporting data and analytic results." For these reason, CPDA opposes the use of proprietary models that are not accessible to the public. The Agency should have to rebut a presumption against transparency when reproducibility is not achieved.

3.5 Does EPA ensure and maximize the quality of information from external sources?

The Agency makes a commitment to ensure the quality and transparency of external information is "sufficient for its intended use." (line 690) CPDA recommends that the Agency impose a uniform standard for information, *consistent with* its intended use. Increasingly, the Agency's actions are based on externally-supplied information, but the Agency's decisions should not vary based on the *source* of information, but rather, the *quality* of information. That is, sound research methods and peer review are appropriate for all information underlying a rule-making. The Agency should impose standards based on the Agency's intended use for the information.

Pre-Dissemination Review (Section 4)

4.1 What are the administrative mechanisms for pre-dissemination reviews?

As we expressed in earlier comments, CPDA believes the Agency's focus in implementing the Data Quality Act should lie in the pre-dissemination process. That is, the bulk of the effort expended in ensuring and maximizing data quality should occur in the policy and procedures which occur before the Agency sponsors information, issues statements, or

promulgates rules regarding information. The pre-dissemination emphasis utilizes Agency resources efficiently and reduces the need for complaints and corrections.

CPDA was thus surprised to read that EPA planned to rely on existing procedures, unmodified, to "ensure and maximize the quality of disseminated information. (lines 580-88) We believe that this approach falls short of the minimum requirements set forth in OMB's Guidelines. OMB's Guidelines, while promoting flexibility appropriate to each Agency's scope and purpose, encourage the *development* of existing procedures to meet the increased requirements of the Data Quality Act. (See 67 Fed. Reg. 8451, 8453) CPDA supports EPA's existing procedures as a starting point for data quality reform, but requests that the Agency explain how the existing procedures ensure information quality, and how the procedures will be revised to meet the Data Quality Act's requirements. The existing policies should be clarified and refined to promote data quality.

Moreover, the Agency's Data Quality Guidelines should explicitly demonstrate the Agency's commitment to quality through every stage information undergoes before dissemination. According to the OMB Memorandum, the stages during which information needs to be protected include creation, collection, maintenance, and dissemination. Each prong of quality, including objectivity, utility, and integrity, must be satisfied at every stage.

Another agency's Draft Guidelines provide an example of how EPA can demonstrate its commitment to data quality. The United States Department of Agriculture's Economic Research Service (ERS) specifies the criteria "at the center of the clearance process." (ERS Draft Guidelines, p. 9) The ERS Guidelines detail the peer review, checks for consistency with both external and internal reference sources, and staff reviews that must take place before ERS will rely upon or release information. EPA should similarly develop its policies to ensure that information is rigorously scrutinized before use. Such processes are incumbent upon the Agency under the Data Quality Act.

Correction of Information (Section 5)

5.1 What are EPA's administrative mechanisms for affected persons to seek and obtain appropriate correction of information?

While the Data Quality Act's primary goal is to ensure that agencies rely on quality information, the Act also provides recourse for persons who are hurt when agencies rely on compromised information. We at CPDA feel strongly that EPA should focus on achieving data quality before dissemination, thereby reducing the reliance on the administrative recourse mechanisms. However, we offer our thoughts regarding efficient recourse mechanisms.

In order to administer an efficient recourse process, we believe the Agency should utilize a "triage" system upon receipt of requests for correction. While all requests should be handled within a specified time frame, the Agency should address more serious complaints, e.g., those alleging economic harm, in an immediate manner.

Also, EPA's Draft Data Quality Guidelines do not specify the time the Agency will have to address requests for correction. The OMB Memorandum emphasizes that agency guidelines should contain procedural specifics. We believe the Agency should reply to requesters within 30 days of receiving a request. While resolution of the request's merits may not always occur within 30 days, the Agency should keep the requester apprised of the Agency's progress on the request.

5.2 Who may request a correction of information from the Agency?

In its recent Memorandum, OMB makes clear that "[t]he focus of the complaint process should be on the merits of the complaint, not on the possible interests or qualifications of the complainant." As the Data Quality Act does not require "standing" or similar burdens of proving one's "affected" status, the Agency should assume the requester is "affected" and allow the requester to present her grievance.

We point out that the affected person almost always bears the burden of demonstrating how the use of information of sub-standard quality affects the complainant. We do not believe requests should be dismissed based on the complainant's relationship to the information; rather, the central focus must be the quality of the information in question.

Further, when a request alleges the Agency did not perform its Data Quality responsibilities with regard to influential information that is not publicly reproducible, the Agency must have to rebut a presumption against transparency with a demonstration of "especially vigorous robustness checks." Again, the Agency should not dismiss unfavorable claims on the basis that the complainant did not meet specific criteria; at a minimum, the Agency should allow the requester to clarify her allegations.

5.3 What should be included in a request for correction of information?

The Agency requests contact information and a reference to either OMB or EPA Data Quality Guidelines on the request for correction. These are reasonable requests which will allow the Agency to address the request and to reply to the submitter. However, as with the above "standing" issue, we do not support any formal criteria for submission of a request for correction.

5.4 Will EPA consider all requests for correction of information?

As the Data Quality Act does not impose statutes of limitations for requests for correction, so the Agency is not authorized to impose such restrictions. What the Agency may deem "frivolous" may represent significant influence for an affected person. Therefore, the Agency should consider and reply to each claim. As mentioned earlier, a triage system will allow the Agency to deal with claims in order of effect on the complainant, but must also ensure that all requests are answered.

CPDA is concerned that the Agency's Draft Guidelines provide that "EPA may consider frivolous any complaint which could have been submitted as a timely comment in the rulemaking or other action but was submitted after the comment period." (lines 749-51) While

the comment period provides an opportunity for requests for correction, the comment period should not impose a de facto statute of limitations for challenging the data quality procedures with regard to the information underlying the rulemaking. Such a policy would be inconsistent with the spirit of the Data Quality Act.

5.5 How will EPA respond to a request for correction of information?

CPDA commends the Agency for committing to reply to all requests for correction. We believe the Agency should specify a time frame for replying to requests.

5.6 Will EPA reconsider its decision on a request for correction of information?

This section of the Agency's Guidelines provides good background on the Agency's approach to appeals, but nevertheless, should be expanded. Presumably, the Agency will develop decision criteria with experience, but the Agency should advise the public as to factors the Agency will weigh in determining whether information should be corrected. The Agency may want to specify timeframes for appeals.

5.7 How does EPA process requests for reconsideration of EPA decisions?

EPA's Guidelines describe an organized process for handling requests for reconsideration. The procedures described are both fixed and flexible, allowing for development through experience. The Agency describes a fair system for assessing appeals.

Ongoing Development of Data Quality Policy, Procedures

CPDA applauds the Agency's effort to involve stakeholders in the implementation of the Data Quality Act. To further this stated objective, CPDA urges EPA to consider stakeholder comments when revising its Guidelines, and to make the next draft, due to OMB by July 1st, publicly available. Making this draft available is consistent with the goal of increased transparency and will ensure that stakeholders have access to the next phase of the data quality process.

While CPDA hoped that the first draft of the Agency's Guidelines would detail the ways in which the Agency planned to improve upon existing procedures, we remain hopeful that the Agency will meet and exceed the minimum requirements of the Data Quality Act and OMB Guidelines. As a concerned stakeholder, CPDA is available to offer further comment to the Agency on any aspect of the upcoming Data Quality Guidelines. CPDA again thanks the Agency for the opportunity to comment.

Sincerely,

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President

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